

physicochemical property is the distribution coefficient between water and phospholipid membranes, the octanol/water distribution coefficient, the molecular weight, the solubility, and/or a combination of these parameters of the substance.

Claim 6 (Canceled)

Claim 7 (Currently amended) Computer system according to Claim 1, wherein the physicochemical properties of test substances and corresponding substance-dependent parameters ~~determined experimentally for the test substances~~ are stored in a the database and are used to obtain a calculation function for prediction of substance-dependent parameters for a new substance to be studied.

Claim 8 (Currently amended) Computer system according to Claim 1, wherein the prediction module includes a calculation function for calculating ~~said at least one parameter~~ the substance-dependent parameters required by the physiological based pharmacokinetic simulation model from the lipophilicity and/or the molecular weight of the substance.

Claim 9 (Original) Computer system according to Claim 8, wherein the calculation function is based on a linear regression of experimentally determined parameter values.

Claims 10-27 (Canceled)

#### REMARKS/ARGUMENTS

This paper is submitted in response to the non-final official action dated August 18, 2008. Claims 1, 7, and 8 are amended and claims 2-4, 6, 10-27 are canceled without prejudice. Reconsideration in view of the Amendment and Arguments presented below is requested.

USSN: 10/714,791  
Reply to Office Action of 10/31/2007

Page 3

**Claim rejections under 35 USC § 101**

The Examiner rejected claims 1-27 because the claimed invention is directed to non-statutory subject matter.

He stated that the computer system would execute certain method steps, which are geared towards “predicting” profiles or parameters. He states further that such method performed by the system would not produce a concrete, tangible and useful result. In his view the “concentration/time profile” does not represent a concrete, tangible and useful result, because in his view it would require significant further interpretation to be used. Applicant disagrees. The proper inquiry or test for determining statutory subject matter as espoused by the Federal Circuit in the recent decision *In re Bilski*, Fed. Cir. 2007-1130, is the machine-or-transformation test. “The machine-or-transformation test is a two-branched inquiry; an applicant may show that a claim satisfies §101 either by showing that his claim is tied to a particular machine, or by showing that his claim transforms an article.” *In re Bilski*, at 24 (emphasis added).

According to claim 1, at least one physicochemical property of a chemical substance is inputted into a computer system and a concentration/time profile of said substance in an insect is obtained. Accordingly, Applicants submit that this specific input is directed to a machine (the computer system) and thereby satisfying the machine prong of the two-part inquiry.

In addition, Applicant submits that the claims provide a concrete result. It is also tangible, since it is outputted for a user and is useful, since just from physicochemical properties the pharmacokinetic behavior of said chemical substance in an insect is obtained. It is known by one of ordinary skill in the art, that from such a concentration/time profile e.g. an optimum dosage of a pesticide easily can be obtained by a read out.

The method claims (10-18) have been canceled withdrawn and similarly, the claims drawn to digital storage media (19-27) have been canceled.

Having established that at least the machine-or-transformation test has been met, and that the claims provide a concrete result, Applicants submit that the presently claimed invention constitutes patent-eligible statutory subject matter and requests that the rejection under 35 U.S.C. §101 be withdrawn.

USSN: 10/714,791  
Reply to Office Action of 10/31/2007

Page 4

**Claim rejections under 35 USC § 112, first and second paragraph**

Claims 1-27 are rejected as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Applicants have amended claim 1 to overcome the rejection. The physicochemical based pharmacokinetic simulation model in claim 1 is described being represented by a system of coupled differential equations, the differential equations describing the mass transport, the distribution, the metabolism and the excretion of chemical substances in said insect on the basis of the following substance-dependent parameters: rate coefficients for mass transport between the organs of said insect, organ/haemolymph distribution coefficients, metabolism rate coefficients, and excretion rate coefficients.

By this amendment the metes and bounds of the physicochemical based pharmacokinetic simulation model should have been made clear. Examples of a system of coupled differential equations describing the mass transport, distribution, metabolism, and excretion of a substance in an insect is given in the specification, pages 6-10.

This amended finds support on page 1 lines 10-22, page 4 lines 6-17, page 5 lines 32-34, page 6 line 1 – page 10 line 12, Fig. 3.

Furthermore claim 1 is amended to point out, that the pharmacokinetic behavior of a chemical substance in an insect is calculated on the basis of at least one physicochemical property of said chemical substance. Support for this amendment can be found e.g. on page 1 lines 26-30, page lines 5-7, page 5 lines 15-17.

Claim 1 has been limited by a further feature: a database containing physicochemical properties and experimentally determined substance-dependent parameters of test substances.

Furthermore it has been made clear, that the calculation of substance-dependent parameters of the chemical substance to be studied, which are required by the physiological based pharmacokinetic simulation model, are calculated by means of the relations stored in said database.

USSN: 10/714,791

Reply to Office Action of 10/31/2007

Page 5

Support for these amendments is given e.g. on page 2 line 31 – page 3 line 6, page 4 line 18 – 31.

In view of the amendment and arguments provided, the rejection under 35 U.S.C. §101, Applicants submit that these rejections under 35 U.S.C. §112 are also overcome.

Accordingly, Applicant claims a computer system for calculating a pharmacokinetic behavior of a chemical substance in an insect is claimed. Further, The computer system comprises an input/output module, a physiological based pharmacokinetic simulation model of an insect, a database and a prediction module. The physiological based pharmacokinetic simulation model is represented by a system of coupled differential equations, the differential equations describing the mass transport, the distribution, the metabolism and the excretion of chemical substances in said insect on the basis of the following substance-dependent parameters: rate coefficients for mass transport between the organs of said insect, organ/haemolymph distribution coefficients, metabolism rate coefficients, and excretion rate coefficients. One of ordinary skill in the art knows how to set up such a system of differential equations. One example is given on pages 6 to 10.

For the calculation of the pharmacokinetic behavior of a substance in an insect, substance-dependent parameters are required by the physiological based pharmacokinetic simulation model. These substance-dependent parameters are calculated from at least one physicochemical property of the substance to be studied. The physicochemical property of the substance to be studied is inputted via the input/output module.

The relations between physicochemical properties and corresponding substance-dependent parameters of test substances, which are stored in the database, are used by the prediction module to calculate substance-dependent parameters from at least one physicochemical property of a substance to be studied.

One of ordinary skill in the art is familiar with methods for calculating a parameter  $A_1$  (substance-dependent parameter) from a given parameter  $B_1$  (physicochemical property) with the aid of known relations between corresponding parameters  $A_n$  and  $B_n$ . One example is given in (amended) claims 8 and 9 as well as Fig. 4, and on page 9 lines 15 to

USSN: 10/714,791  
Reply to Office Action of 10/31/2007

Page 6

27.

On the basis of the substance-dependent parameters of a substance to be studied concentration/time profiles of said substance are calculated by physiological based pharmacokinetic simulation model and are outputted via the input/output module. Thereby a concrete, tangible and useful result is obtained.

One of ordinary skill in the art knows, how to obtain concentration/time profiles from a simulation model as described, when the parameters required by the simulation model are calculated.

Applicants submit that claim 1, as amended, now clearly recites a practical application for the present claimed invention. Additionally the subject matter which applicant regard as the invention is now particularly pointed out and distinctly claimed in amended claim 1. Consequently, the rejection under 35 U.S.C § 112 should be overcome.

Claims 2-4, and 6 have been canceled. Independent claims 7 and 8 have been adapted to amended claim 1 and thus also have overcome the rejection under 35 U.S.C. § 112. Independent claims 5 and 9 have not been amended but should be clear in relation to amended claims 1 and 8, now.

The method claims (10-18) and claims drawn to digital storage media (19-27) have been canceled.

Thus, the rejections should be withdrawn and the case should go to issue.

USSN: 10/714,791  
Reply to Office Action of 10/31/2007

Page 7


**CONDITIONAL PETITION FOR EXTENSION OF TIME**

If entry and consideration of the amendments above requires an extension of time, Applicants respectfully request that this be considered a petition therefore. The Assistant Commissioner is authorized to charge any fee(s) due in this connection to Deposit Account No. 14-1263.

**ADDITIONAL FEE**

Please charge any insufficiency of fees, or credit any excess, to Deposit Account No. 14-1263.

Respectfully submitted,  
NORRIS McLAUGHLIN & MARCUS, P.A.

By   
Christa Hildebrand  
Reg. No. 34,953  
875 Third Avenue - 18<sup>th</sup> Floor  
New York, New York 10022  
Phone: (212) 808-0700  
Fax: (212) 808-0844  
Facsimile: (212)808-0844

USSN: 10/714,791  
Reply to Office Action of 10/31/2007

Page 8